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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,454	09/13/2001	Nilgun E. Tumer	OCIRS-073	4316
7590 10/06/2003			EXAMINER	
Lerner David Littenberg Krumholz & Mentlik 600 South Avenue West Westfield, NJ 07090			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,454	TUMER ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 13 September 2001 is: a) ☒ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group XV, claims 33-36, filed July 28, 2003, is acknowledged. Claims 1-32 are withdrawn from consideration as being directed to nonelected inventions.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed September 13, 2001, and August 5, 2002, are attached to the instant Office action.

Claim Objections

Claim 33 is objected to because of the following informalities: in line 3, the word "cell" is misspelled as "call". Appropriate correction is required.

Claim 34 is objected to because of the following informalities: in line 2, the use of the indefinite article "an" before "ethionine" appears to be improper or unintentional. Appropriate correction is required.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1638

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for selecting transgenic plants that express a cystathionine gamma synthase, does not reasonably provide enablement for a method of selecting transgenic plant cells that express a cystathionine gamma synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a chimeric nucleic acid comprising a promoter functional in a plant cell operably linked to a first DNA molecule of interest and a second DNA molecule encoding a cystathionine gamma synthase, and to a method of selecting a plant cell by transforming said cell with said chimeric nucleic acid.

The specification discloses *Agrobacterium*-mediated transformation of potato plant cells with a chimeric nucleic acid comprising a CaMV 35S promoter operably linked to a DNA molecule encoding an *Arabidopsis* cystathionine gamma synthase, followed by selection of transformed cells on media containing kanamycin, and regeneration of transgenic plants from said transformed cells. The specification additionally discloses that the root growth of transgenic potato plants expressing the *Arabidopsis* cystathionine gamma synthase was not inhibited at concentrations of ethionine (10 uM) that inhibited the root growth of nontransgenic plants, and that transgenic potato plants expressing the *Arabidopsis* cystathionine gamma synthase exhibited limited root growth at higher concentrations of ethionine (25 and 50 uM). The

specification does not disclose, however, the effect of expressing cystathionine gamma synthase on the growth of plant cells in culture, or what concentrations of ethionine have an inhibitory effect on plant cell growth.

Guidance for making and using the claimed invention is necessary because it is unpredictable whether ethionine could be used to select cystathionine gamma synthase transformed cells in culture, as the sensitivity of cells in culture to a selective agent such as ethionine may differ from the sensitivity of cells in a regenerated plant part such as roots. For example, Inaba et al. teach that cellular ethionine resistance is thought to be due to the presence of excess soluble methionine in the cell, which dilutes exogenously applied ethionine (Plant Physiology, 1994, Vol. 104, pages 881-887, Applicant's IDS, see page 881 column 2 first full paragraph). Inaba et al. also teach that the in vivo activity of cystathionine gamma synthase, which catalyzes transsulfuration of O-phosphohomoserine to produce the methionine precursor cystathionine, is decreased upon the addition of methionine to culture media (page 881 column 2 first paragraph). Inaba et al. additionally teach that the level of methionine varies between different plant tissues and at different times during plant development (page 885 Figures 3 and 4). Accordingly, cystathionine gamma synthase transformed cells in culture may not be amenable to ethionine selection, as the cellular levels of methionine and/or O-phosphohomoserine in cultured cells may not allow for the production of methionine in quantities sufficient to confer resistance to ethionine. In light of this unpredictability, it would require undue experimentation to determine the particular culture conditions, if any, that would allow for the selection of cystathionine gamma synthase transformed cells, as the effect of

different concentrations of ethionine and possibly methionine and/or O-phosphohomoserine in culture would have to be tested.

Given the unpredictability of using ethionine to select cystathionine gamma synthase transformed cells in culture, and given the lack of guidance as discussed above, it would require undue experimentation for one skilled in the art use ethionine to select cystathionine gamma synthase transformed cells.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 35 and 36, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33, 35 and 36 are indefinite in the recitation of "would be". It is unclear at what point in time the ethionine would be toxic to a plant cell, as "would be" implies an unspecified future time.

Claim 36 is indefinite in the recitation of "and first DNA molecule of interest and said second DNA molecule encoding a cystathionine gamma synthase". It is unclear from the claim language whether both the first and second DNA molecule encode a cystathionine gamma synthase, or whether only the second DNA molecule encodes a cystathionine gamma synthase.

Claims 33 and 36 are indefinite in that the claims indicate that only one promoter is operably linked to two distinct nucleic acid sequences. It is unclear how one promoter

would control the expression of two distinct nucleic acid sequences in a plant cell, as eukaryotic expression systems are generally monocistronic.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Falco et al. (US Patent No. 5,912,414, issued June 15, 1999 and having a § 102(e) date of November 8, 1996).

The claims are drawn to a chimeric nucleic acid comprising a promoter functional in a plant cell operably linked to a first DNA molecule of interest and a second DNA molecule encoding a cystathionine gamma synthase, and to a transformed plant cell comprising said chimeric nucleic acid molecule.

Falco et al. teach chimeric nucleic acids comprising a globing 1 or glutei 2 promoter, a bar gene, and a DNA molecule encoding a corn cystathionine gamma synthase, and transformed corn plant cells comprising said chimeric nucleic acid molecules (column 27 line 25 through column 29 line 33; column 32 line 1 through column 34 line 12; columns 61-64).

Remarks

No claim is allowed.

Claims 35-36 are deemed free of the prior art due to the failure of the prior art to teach or suggest a method of selecting a plant cell by transforming said cell with a chimeric nucleic acid encoding a cystathionine gamma synthase.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CC
September 26, 2003

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600